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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/753,907	09/03/91	PALMER	REF/C0221

EXAMINER
ROSE,S

ART UNIT	PAPER NUMBER
1205	6

DATE MAILED: 03/10/92

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on ______ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ______ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ ______.

Part II SUMMARY OF ACTION

1. ☒ Claims 12 & 22 are pending in the application.

   Of the above, claims ______ are withdrawn from consideration.

2. ☒ Claims 1 & 71 have been cancelled.
3. ☐ Claims ______ are allowed.
4. ☒ Claims 12 & 22 are rejected.
5. ☐ Claims ______ are objected to.
6. ☐ Claims ______ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on ______. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on ______, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed ______, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☒ been filed in parent application, serial no. 578661; filed on 9/07/90.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Skidmore et al. (Glaxo), Gt. Br. 2,140,800 Dec. 5, 1984 and Jepson et al, Chem. Abst. 110:147583 (1989) are at least two prior art instances wherein persons skilled in the art were taught prior to applicants' priority date to replace salbutamol with salmeterol for the inhalation therapeutic advantage of longer action instead of short duration. Neither describes salmeterol in combination therapy with a steroid as is conventional for inhalation by asthmatics.

Hunt et al. (Glaxo), Gt. Br. 2,107,715 May 5, 1983 describes pressurized aerosol or dry powder cartridge combination inhalation therapy with the steroid become salbutamol (Ex. 6) or another bronchodilator.

Cairns, Gt. Br., 2,187,953 Sept. 23, 1987 is similar to Hunt et al. for such combination therapy.

Radhakrishon, U.S. 4,906,476 (filed 12/14/88), (as of that date) establishes art-recognized equivalency for inhalation therapy, not only of steroids such as beclomethasone dipropionate and fluticasone propionate, but also of salmeterol and salbutamol.

S.N. 578,606, with 7 claims, has been refiled as S.N. 753,906, with claims 12 to 22. S.N. 578,601, with 7 claims, has been refiled as 753,907, with claims 12 to 22. In view of the art recognized equivalency of the steroids, as noted above, the common invention concept of both cases involves no more than the

prior art teaching, of Skidmore et al. and Jepson et al, to replace salbutamol with salmeterol, in otherwise conventional asthma inhalation combination therapy with a steroid known to be effective for this purpose.

Claims 12 to 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12 to 22 of copending application Serial No. 353,906. Although the conflicting claims are not identical, they are not patentably distinct from each other because art-recognized equivalency of the steroids and of salmeterol to salbutamol, as established in the record by each of Skidmore et al, Jepson et al. and Radhakrishan (as of 12/14/88), and the known combination inhalation asthma therapy shown by Hunt et al. and Cairns.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Rose:st
March 09, 1992

Shep Rose

SHEP K. ROSE
EXAMINER
ART UNIT 125